K062382

SEP 27 2006

Date: August 14, 2006

510(k) Summary

1. 510(k) owner (submitter)

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in U.S.	Koji Nishida KURARAY AMERICA INC. 600 Lexington Avenue, 26th Floor New York, NY 10022 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

2. Name of Device

1) Trade / Proprietary name	CLEARFIL DC BOND
2) Classification name	Resin tooth bonding agent (21 CFR section 872.3200. Product code: KLE)
3) Common name	Resin-based dental adhesive system

3. Predicate device

1) CLEARFIL TRI-S BOND	510(k) Number:	K042913
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	KURARAY MEDICAL INC.
2) CLEARFIL LINER BOND 2V	510(k) Number:	K012440
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	KURARAY MEDICAL, INC.
3) CLEARFIL PHOTO BOND	510(k) Number:	K012432
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	KURARAY MEDICAL, INC.

4. Description of device

CLEARFIL DC BOND is a dual-cure (light- and /or self-cure), two-component, one-step bonding system that allows simultaneous treatment of both dentin and enamel. It is classified into Resin tooth bonding agent, 21 CFR Section 872.3200, because it is a device composed of materials such as dimethacrylate monomers intended to promote adhesion of restorative material to dentin, enamel, and metal.

5. Intended use of device

CLEARFIL DC BOND, the applicant device, is intended to be used for the indications listed in the left hand column of the below table that are equivalent to those of the predicate devices.

Table 3-1: Indications for Use and predicate devices

Indications for Use	Predicate devices
1) Core build-ups using light-, dual-, or self-cure composite resin	CLEARFIL LINER BOND 2V (in conjunction with CLEARFIL DC CORE AUTOMIX*)
2) Direct restorations using light-cure composite resin	CLEARFIL TRI-S BOND, CLEARFIL PHOTO BOND CLEARFIL LINER BOND 2V
3) Direct restorations using self-cure composite resin	CLEARFIL LINER BOND 2V
4) Cavity sealing as a pretreatment for indirect restorations	CLEARFIL TRI-S BOND, CLEARFIL LINER BOND 2V
5) Treatment of exposed root surfaces	CLEARFIL TRI-S BOND, CLEARFIL LINER BOND 2V
6) Intraoral repairs of fractured crowns/bridges made of porcelain, ceramics, hybrid ceramics or composite resin	CLEARFIL TRI-S BOND, CLEARFIL LINER BOND 2V

* CLEARFIL DC CORE AUTOMIX: K043177, manufactured by KURARAY MEDICAL INC. CLEARFIL DC CORE AUTOMIX is intended to be used for core build-ups and is indicating the use of CLEARFIL LINER BOND 2V in its Instructions for Use.

6. Technological characteristics of device

It can be said that CLEARFIL DC BOND, the applicant device, is as safe and effective and performs as well as or better than the predicate devices with the followings:

1) Chemical ingredients

All the chemical ingredients of the applicant device have been used in the predicate devices indicating that the safety of the applicant device is substantially equivalent to the predicate devices.

2) Effectiveness / Performance

Tensile bond strength and marginal sealing characteristic (microleakage) tests performed on the applicant device have demonstrated that the applicant device is more effective and performs better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2006

Kuraray Medical, Incorporated
C/O Mr. Koji Nishida
Kuraray America, Incorporated
600 Lexington Avenue, 26th Floor
New York, New York 10022

Re: K062382
Trade/Device Name: Clearfil™ DC Bond
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: August 14, 2006
Received: August 24, 2006

Dear Mr. Nishida:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

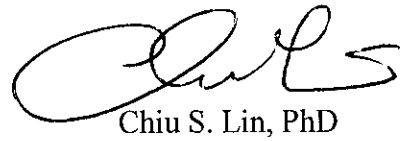
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062382

Device Name: CLEARFIL DC BOND

Indications for Use:

1) Core build-ups using light-, dual-, or self-cure composite resin
2) Direct restorations using light-cure composite resin
3) Direct restorations using self-cure composite resin
4) Cavity sealing as a pretreatment for indirect restorations
5) Treatment of exposed root surfaces
6) Intraoral repairs of fractured crowns/bridges made of porcelain, ceramics, hybrid ceramics or composite resin

Prescription Use ____X____ AND/OR Over-The-Counter Use __N/A__

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...n Sign-Off)
...ion of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number K062382